

### **REMARKS**

Claims 1-19 and 26-29 were rejected. Claims 1, 9, 13, 14, 17, 26 and 29 have been amended and claims 2-8, 11, 12, 15, 16, 18-25, 27-28 and 30-38 are canceled. Claims 39 and 40 are new. None of the amended or new claims introduce new subject matter. Claim 40 is supported at p. 1, lines 8-10 and p. 21, line 16 to p. 22, line 17. The limitations of the canceled claims have been incorporated into the amended claims. Claims 1, 9, 10, 13, 14, 17, 26, 29 39 and 40 are pending. It is believed that these amendments put all the claims in condition for allowance. In addition, the Examiner's remarks on the claim rejections are responded to below.

### **35 U.S.C. § 112 – Written Description**

Claims 1-19 and 26-29 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Applicant traverses the rejection.

The grounds for the rejection included the following statement:

“While having written description for dibenzo-alpha-pyrone identified in the specification tables and/or examples, the specification is void of specific peptides, organic molecules (lipids and chromo-peptides) that qualify for the functional characteristics claimed as the biomolecules. The claimed and disclosed molecular structure is merely a potential structure based on chemical and not structural determination.”

The claims recite specific structural elements of the composition rather than reciting elements by mere statements of function. The specification states that the identities of the colored compounds (carotenoids) were established by HPLC using authentic markers. (Page 4, lines 18-29). Thus, the limitation directed to the identity of the chromopeptides was proven in the laboratory and rebuts the examiner's argument that there is not a specific example that discloses a DBP with specific chromoproteins. Amended claim 1 specifies these chromopeptides.

The Examiner stated that “there is not a specific example of a compound comprising a dibenzo-alpha-pyrone that discloses specific chromo-proteins, lipids, and the various functional groups claimed for the dibenzo-alpha-pyrone moiety.” There is a specific example. The formula shown on pages 5 and 6 of the specification provides a clear depiction to support a claim for a composition of isolated dibenzo-alpha-pyrone chromoproteins as claimed in independent claims

1 and 26. The formula provides the structure of the dibenzo-alpha-pyrone moiety and provides for alternative choices of substituents. Furthermore the formula provides for various species of lipids having fatty acyl esters of glycerol. Disclosure of specific chromoproteins is found in the reduction to practice description of Example 4 (page 22), wherein two chromoproteins are described by a combination of identifying characteristics.

The Examiner stated that "the presumed structure example does not share a common core structure, as creatine (and other functional moieties) can be presumably connected to R<sup>3</sup> or R<sup>8</sup> without any evidence." Here, the fact that the claim provides for creatine at the R<sup>3</sup> or R<sup>8</sup> positions is not a lack of written description, since these two structures are described in the specification, e.g., at page 2, line 20, et seq. Second, it is not the case that these structures were provided without any evidence. The specification describes that saponification of the larger molecule provided smaller molecules which were identified and interpretation of the data led to the determination of the structure of the larger DCP. The specification describes that saponification resulted in the occurrence of creatine (page 5, line 7 et seq.).

The Examiner stated that "while having written description for dibenzo-alpha-pyrone identified in the specification tables and/or examples, the specification is void of specific peptides, organic molecules (lipids and chromo-peptides) that qualify for the functional characteristics claimed as the biomolecules".

The claims are directed to a composition of isolated DCPs that are claimed by means of definite constituents, not by functional characteristics. The Examiner has conceded that there is sufficient written description of the dibenzo-alpha-pyrones. The other constituents of the DCPs of the independent claims include phosphocreatine; chromo-peptides of molecular weights of about  $\leq 2$  KD; and lipids having fatty acyl esters of glycerol. These are not constituents described in terms of their functional characteristics. These are descriptions of definite biological substituents that one of skill in the art would recognize, and the specification provides formulas, description and reduction to practice of these constituents. Thus the written description requirement is satisfied.

The Examiner stated that "the claimed and disclosed molecular structure is merely a potential structure based on chemical and not structural determination." First, patentability of a

product cannot be denied on the basis of the method of making it. It doesn't matter whether the claimed molecular structure was conceived as a result of chemical or structural analysis. Furthermore, the claimed and disclosed molecular structure is not a "potential structure," it is definite. It is presented as a structural formula with definite options for the constituents. So long as one skilled in the art would understand what that structure is, the written description requirement is satisfied.

The Examiner's grounds to support the rejection also included the following:

Lipase reactions "suggested" that lower MW lipids were present and that higher MW proteins, "like B-48" might be present in dibenzo-alpha-pyrone, see pages 23 and 24 of the specification. The "suggestion" that "dibenzo-alpha-pyrone are associated with low/medium weight lipoproteins is also indicative of the molecule not being completely described as to have proper written description. Thus, there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Accordingly, it is maintained that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

It appears, from these remarks that the Examiner's basis for the rejection is based on the drafter's choice of the term "suggested." Applicant argues that this is a case of rejecting form over substance. The inventor determined the claimed structure based on experimental procedures and has provided evidence of the results in figures 2, 3, and 4 and in the examples. B-48 is not a claimed substituent, so criticism of the description of B-48 does not constitute proper grounds for the rejection. Low/medium weight lipoproteins are not a claimed constituent. What is claimed as a constituent is fatty acyl esters of glycerol, of carbon chain length about C<sub>14</sub> to about C<sub>24</sub>. This is supported by description of the lipase degradation reaction that liberated phospholipids containing C<sub>14</sub>-C<sub>24</sub> fatty acids (page 4, line 30 et seq.)

For all the above reasons, Applicant submits that the claims are supported by adequate written description. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

**35 U.S.C. § 112 – Enablement**

Claims 1-19 and 26-29 are rejected under 35 U.S.C. § 112, first paragraph, because the Examiner alleges the specification, while being enabling for a composition of a fractionated extract of Shilajit, does not reasonably provide enablement for the specific compositions claimed. Applicant traverses the rejection.

The Examiner stated that it is well known that Shilajit and Shilajit extracts contain dibenzo-alpha-pyrone. The Examiner stated that since the core structure that is correlated with the pharmaceutical function remains largely unsolved, means for determining both is highly unpredictable. Applicant disagrees. The structure was determined using scientific methodology known to those of skill in the art including enzymatic reactions to degrade the large molecules into constituent compounds and chromatographic analyses with interpretation of the results in a standard manner. The structure and methodology used are described in the specification. The described methodology is not unpredictable.

The Examiner included remarks which also appeared as grounds for the written description rejection. The Examiner stated that “the specification has provided an alleged structure, or best guess of a generic. However the specification does not provide specific examples of the claimed compounds.” Response to these objections has been provided in the previous section on written description. Applicant has pointed out that all claimed limitations are supported by scientific evidence and scientific interpretation of the evidence. The completeness of the description of unclaimed constituents is not relevant to the determination of patentability. Specific examples of the claimed compounds are, indeed, provided, for example by provision of the formula at page 5, line 14 et seq.

For all the above reasons, Applicant submits that the claims are supported by adequate enabling disclosure and Applicant respectfully requests that the rejection be reconsidered and withdrawn.

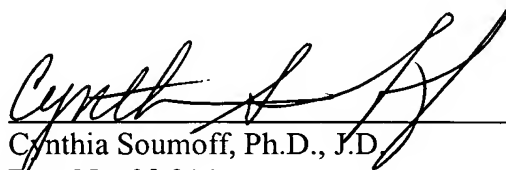
**35 U.S.C. § 102**

Claims 1-19 and 26-29 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,405,613 to Rowland. Rowland discloses compositions of Shilajit or aqueous Shilajit extracts in combination with vitamins as a pharmaceutical or nutritional supplement. Amended claims 1 and 26 are directed to isolated formulations and do not use the "comprising" terminology. Thus, the claims are not directed to natural Shilajit or to the extracts of natural Shilajit, as taught by Rowland. Rowland does not disclose an isolated composition of dibenzo-alpha-pyrone chromoproteins, as in the claimed invention. Other prior art, while disclosing that dibenzo-alpha-pyrone is an important constituent of Shilajit, does not describe the claimed isolated dibenzo-alpha-pyrone chromoproteins. For this reason Applicant requests that the rejection be reconsidered and withdrawn.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

Dated: January 10, 2007

  
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